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Standard Specification for Total Elbow Prostheses[1]

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1. Scope

1.1 This specification covers total elbow replacement (TER) prostheses and hemi-elbow replacement ("hemi") prostheses used to provide functioning articulation by employing humeral, ulnar, and/or radial components that allow for the restoration of motion of the human elbow joint complex.

1.2 Included within the scope of this specification are elbow prosthesis components for primary and revision surgery with linked and non-linked designs and components implanted with or without use of bone cement.

1.3 This specification is intended to provide basic descriptions of material and prosthesis geometry. In addition, those characteristics determined to be important to the *in vivo* performance of the prosthesis are defined. However, compliance with this specification does not itself mean that a device will provide satisfactory clinical performance.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F451 Specification for Acrylic Bone Cement

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

F746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

F983 Practice for Permanent Marking of Orthopaedic Implant Components

F1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings

F1108 Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)

F1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings

F1160 Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings

F1223 Test Method for Determination of Total Knee Replacement Constraint

F1377 Specification for Cobalt-28Chromium-6Molybdenum Powder for Medical Devices (UNS R30075, UNS R31537, and UNS R31538)

F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

F1580 Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants
F1814 Guide for Evaluating Modular Hip and Knee Joint Components
F2759 Guide for Assessment of the Ultra-High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices

2.2 *ISO Standards:*[3]
ISO 5832-3 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy
ISO 5832-4 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy
ISO 5832-12 Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy
ISO 5834-2 Implants for Surgery—Ultra High Molecular Weight Polyethylene—Part 2: Moulded Forms
ISO 6018 Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling
ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process
ISO 14243-1 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 1: Loading and Displacement Parameters for Wear-testing Machines with Load Control and Corresponding Environmental Conditions for Test
ISO 14243-2 Implants for Surgery—Wear of Total Knee-joint Prostheses—Part 2: Methods of Measurement
ISO 14243-3 Implants for Surgery—Wear of Total Knee-joint Prostheses—Part 3: Loading and Displacement Parameters for Wear-testing Machines with Displacement Control and Corresponding Environmental Conditions for Test

2.3 *FDA Documents:*[4]
21 CFR 888.3150 Elbow Joint Metal/Polymer Constrained Cemented Prosthesis
21 CFR 888.3160 Elbow Joint Metal/Polymer Semi-constrained Cemented Prosthesis
21 CFR 888.3170 Elbow Joint Radial (Hemi-elbow) Polymer Prosthesis
21 CFR 888.3180 Elbow Joint Humeral (Hemi-elbow) Metallic Uncemented Prosthesis
21 CFR 888.6 Degree of Constraint
Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements
Guidance Document for Testing Non-articulating, Mechanically Locked Modular Implant Components
Class II Special Controls Guidance Document Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA

2.4 *ANSI/ASME Standard:*[3]
ANSI/ASME B46.1-1995 Surface Texture (Surface Roughness, Waviness, and Lay)

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *bearing surface, n*—part of the prosthetic component that articulates against the counter surface of the natural or prosthetic elbow joint.

3.1.2 *extension, n*—rotation of the ulna and radius away from the humerus around the elbow joint axis in the sagittal plane.

3.1.3 *flexion, n*—rotation of the ulna and radius towards the humerus around the elbow joint axis in the sagittal plane.

3.1.4 *hemi-elbow replacement (hemi), n*—prosthetic part that substitutes for the natural humero-ulnar, radio-ulnar, and/or humero-radial articulating surfaces in the human elbow in which only one half of the articulating surfaces is replaced. The prosthesis is expected to articulate with the remaining natural biological surface(s).

3.1.5 *humeral component, n*—component fixed to the humerus for articulation with the natural or prosthetic ulnar and/or radial component(s), typically consisting of two major components: a fixation stem, and a bearing surface.

3.1.6 *interlock, n*—mechanical design feature used to increase the capture of one component within another to restrict unwanted displacement between components (that is, locking mechanism for modular components such as a bearing surface to a metallic stem component).

3.1.7 *laxity, n*—intentional looseness in the fit between linked style elbow prosthetic components (typically the humero-ulnar components) that allows small, secondary out-of-plane motions during primary motion to avoid a “fully constrained” or “rigid” connection.

3.1.8 *linked, n*—a style of total elbow prosthesis in which the humeral and ulnar components are physically connected by a linking mechanism to prevent disassociation (dislocation) while allowing motion in selected directions.

3.1.9 *non-linked, n*—a style of total elbow prosthesis in which the humeral and ulnar components are not physically connected by a linking mechanism. These components rely on soft tissue or another mechanism to minimize the potential for disassociation (dislocation) of the two components.

3.1.10 *pronation, n*—rotation of the radius medially about the ulna around a superior-inferior axis.

3.1.11 *radial component, n*—component fixed to the radius for articulation with the natural or prosthetic humeral and/or ulnar component(s), typically consisting of two major components: a fixation stem and a bearing surface.

3.1.12 *subluxation, n*—instability or partial dislocation which occurs when the relative translational or rotational motion between the humeral and ulnar components reaches an extreme where the two components would cease to articulate over the designated low-friction bearing surfaces.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[4] Available from Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, http://www.fda.gov.

3.1.13 *supination, n*—rotation of the radius laterally about the ulna around a superior-inferior axis.

3.1.14 *total elbow replacement (TER), n*—prosthetic parts that substitute for, at a minimum, the natural opposing humeral and ulnar articulating surfaces in the human elbow. This includes both humero-ulnar type devices that are intended to function with or without the natural radial head and humero-ulnar with humero-radial option type devices that are intended to replace all three natural articular surfaces of the elbow.

3.1.15 *ulnar component, n*—component fixed to the ulna for articulation with the natural or prosthetic humeral and/or radial component(s), typically consisting of two major components: a fixation stem and a bearing surface.

3.1.16 *valgus, n*—deviation of the ulna away from the midline of the body in the frontal plane.

3.1.17 *varus, n*—deviation of the ulna towards the midline of the body in the frontal plane.

4. Classification

4.1 The following classification by degree of constraint is suggested for all total joint prostheses including total elbow replacement systems based on the concepts adopted by the U.S. Food and Drug Administration (21 CFR 888.6, 21 CFR 888.3150, 21 CFR 888.3160, 21 CFR 888.3170, 21 CFR 888.3180; see 2.3).

4.1.1 *Constrained*—A "constrained" joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

4.1.2 *Semi-Constrained*—A "semi-constrained" joint prosthesis is used for joint replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage.

4.1.3 Currently, most TERs are considered either semi-constrained or constrained. However, devices within a particular classification may allow various degrees of freedom (that is, translation(s) and rotation(s)). Currently, TERs which contain a linkage mechanism are classified as "constrained" per 4.1.1 yet these devices are often referred to as "sloppy hinge" or "linked, semi-constrained" in the peer-reviewed literature in reference to the laxity built into the linkage mechanism to prevent a completely constrained (rigid) connection. These types of devices allow some amount of varus/valgus and rotary motion between the humeral and ulnar components in addition to the primary flexion/extension motion. Devices without this additional laxity are often referred to as "fully constrained" in the literature. See X2.4 for additional discussion.

5. Material

5.1 The choice of materials is understood to be a necessary but not sufficient assurance of function of the device made from them. All devices conforming to this specification shall be fabricated from materials with adequate mechanical strength, durability, corrosion resistance, biocompatibility, and wear resistance.

5.1.1 *Mechanical Strength*—Various metallic components of elbow replacement devices have been successfully fabricated from materials, as examples, found in ASTM Specifications F75, F90, F136, F799, F1108, F1377, F1472, and F1537 and ISO 5832-3. Polymeric bearing components have been fabricated from ultra-high-molecular-weight polyethylene (UHMWPE) as an example, as specified in Specification F648, Guide F2759, or ISO 5834-2. Porous coatings have been fabricated from example materials specified in Specifications F75, F136, F1377, and F1580. Not all of these materials may possess sufficient mechanical strength for critical, highly stressed components or for articulating surfaces. Conformances of a selected material to its standard and successful clinical usage of the material in a previous implant design are not sufficient to ensure the strength of an implant. Manufacturing processes and implant design can strongly influence material properties and performance. Therefore, regardless of the material selected, the elbow prosthesis shall meet the performance requirements of Section 6 of this specification.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopaedic implant application shall be determined to exhibit corrosion resistance equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Test Method F746. If the corrosion resistance of a material is less than one of the materials listed in 5.1.1 when tested in accordance to Test Method F746, its use shall be justified.

5.1.3 *Biocompatibility*—The biocompatibility of materials used shall be evaluated using a risk-based approach such as that outlined in ISO 10993-1. Practice F748 or ISO 10993 provide guidance on types of biologic tests to perform on materials.

5.1.4 *Friction Characteristics*—Bearing surface material couples with limited or no history of successful use for orthopaedic implant application shall be determined to exhibit equal or better performance than one of the material couples listed in 5.1.1 when tested in a pin-on-flat or pin-on-disk test apparatus such as described in Test Method F732 with adequate controls for comparison. A number of different load levels may be used to cover the range of anticipated stresses between articulating components.

NOTE 1—Clinically successful elbow prostheses have utilized either CoCrMo alloy or Ti alloy articulating against UHMWPE. The wear behavior of Ti alloy articulating against UHMWPE in the presence of a third body (for example, bone or bone cement particles) has been demonstrated to be less than that of CoCrMo alloy articulating against UHMWPE under similar conditions. Therefore, appropriate surface treatments of the Ti alloy surface should be considered to improve wear performance of a Ti alloy/UHMWPE bearing couple in the presence of a third body as described in Section 7-J of Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.

6. Performance Requirements

6.1 *Component Function*—Each component for total elbow replacement or hemi-elbow replacement is expected to function as intended when manufactured in accordance with good manufacturing practices and to the requirements of this specification. The components shall be capable of withstanding